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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/707,685
Filing Date: November 07, 2000
Appellant(s): PALMAZ ET AL.

MAILED
JUN 20 2007
GROUP 3700

Paul J. Lee (Registration No.52,420)
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed April 30, 2007 appealing from the Office action mailed November 2, 2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

1. U.S. Patent Application Serial No. 09/716,146 to Boyle et al., filed November 17, 2000.
2. U.S. Patent Application Serial No. 09/783,633 to Bailey et al., filed February 14, 2001.
3. U.S. Patent Application Serial No. 10/258,087 to Boyle et al., filed August 19, 2003.
4. U.S. Patent Application Serial No. 10/672,695 to Boyle et al., filed September 26, 2003.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows:

WITHDRAWN REJECTIONS

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner: The 112 first paragraph rejection over claims 39-53 and 67-74.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

2003/0018381 A1	Whitcher et al.	01-2003

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 39-53 and 67-74 are rejected under 35 U.S.C. 102(e) as being anticipated by Whitcher et al. (Pub.No. US 2003/0018381 A1, cited previously). Referring to claims 39 and 67, Whitcher discloses a method of manufacturing an endoluminal stent (100) capable of radially

expanding from a first diameter to a second diameter and having a plurality of first and second structural elements (see interconnected struts in fig.2 or 3 for example), defining a longitudinal axis and circumferential axis of the stent comprising the steps of vacuum depositing (vacuum deposition is a form of vapor deposition, specifically sputtering and ion beam deposition processes used within a vacuum chamber, which are the same type of vacuum deposition processes used by the applicant, are disclosed by Whitcher, see P0034-P0037) a stent forming metal (120) onto an unpatterned, exterior surface of a generally cylindrical substrate (105) under process conditions (temp, pressure, rate [0035, 0036, 0037]) *selected* (a temp, pressure and rate is disclosed to be selected) to minimize the formation of chemical and intra and inter-granular precipitates in the bulk material of a deposited tubular unpatterned metal crystalline film (115; Whitcher discloses deposition of either an amorphous OR *a crystalline film*, see P0038-P0040, P0043, P0049, P0061, example 1), defining the plurality of first and second structural elements of the stent in the unpatterned metal film, and removing the stent from the substrate [0051, 0052, 0053].

Referring back to the limitation, process condition "selected to minimize" granular precipitates, granular precipitates are categorized in the applicants specification as one of the many "material properties" that are collectively controlled by deposition, see pg.10, lines 12-16. The applicant's specification discloses that the collection of material properties, including the granular precipitates, are controlled or minimized by the actual deposition process, see pg.11, lines 11-15; pg.11 line 30-pg.12, line 2; pg.12, lines 11-13; pg.14, lines 1-12, 19-21. That is, Applicant's disclosure points simply to a vacuum deposition process (sputtering and ion-beam evaporation; pg.11, lines 11-24) as *the means for minimizing precipitates* and other material

properties. Although Whitcher does not explicitly recite granular precipitates, Whitcher does disclose use of the same vacuum deposition processes (sputtering, ion beam deposition, etc., P0034-P0037) and the use of the same materials used by the applicant (P0062) therefore, and discloses such processes control material properties (P0011, P0028), inherently Whitcher is controlling and minimizing material properties such as granular precipitates just as much as the applicants are.

Further, Whitcher specifically discloses *accurately and precisely controlling* the composition and microcrystal structure to have the desired mechanical properties [P0011, 0028, 0038, 0042, 0043], therefore, inherently the granular precipitates are controlled, since granular precipitates are an element of a materials microstructure and the material's mechanical properties, the microstructure and properties which are disclosed to be controlled.

Additionally, Whitcher discloses *selection* of a process *condition*. Whitcher discloses selection of a temperature, pressure, and rate during deposition, therefore, inherently the precipitates are being controlled, since amount and size of the granular precipitates are dependent upon temp, pressure, and rate (general process conditions of vacuum deposition, which applicant has disclosed to be the method of minimizing precipitates), and upon selection of these conditions, one has *controlled* the crystal structure outcome of the metal, hence controlled how much formation of precipitates has occurred. Because Whitcher has disclosed a temperature, pressure, and rate, hence the material properties are preselected and are being controlled by the *selection*. Also, every metal has a specific granular makeup, including precipitates, and just by the user *selecting* a specific material to be deposited, the user is *controlling* the grain size, grain phase, granular precipitates, composition, and binding sites etc.

Further, applicant noted in their previous arguments, inherently precipitates are formed in all post treatments such as annealing. Since some of Whitcher's methods disclose depositing a crystalline film, without the use of annealing process, no precipitates would be formed in the first place, thus are already minimized, since no annealing has taken place and the deposited film is crystalline.

Also, applicant has claimed "process conditions selected to *minimize formation* of chemical and intra and inter-granular precipitates", however they have not claimed to what extent (numerical value) such properties are minimized to. No numerical amount has been assigned to "minimized". It is vague and arbitrary what amount "minimize" is and how it should be examined. It is unclear how to interpret such a word, with no exact value. As best as can be interpreted, Whitcher is believed to have "minimized" formation of precipitates, since the disclosed film may be crystalline upon deposition, since crystalline, would have no precipitates.

Referring to claims 40 and 68, Whitcher discloses depositing a sacrificial material layer (130) onto the substrate (105) prior to vacuum deposition and removing the sacrificial layer in order to remove the stent from the substrate [P0053].

Referring to claims 41-45 and 69-72, Whitcher discloses vacuum deposition by ion beam assisted evaporation, sputtering, in the presence of an inert gas [P0034, P0035, P0036, P0037].

Referring to claims 45 and 73, Whitcher discloses a deposition rate no less than 20 nm/sec ([P0035], > 0.05 mm/min).

Referring to claims 46 and 74, Whitcher discloses rotation of the substrate during deposition ([P0035], rotate or translate the substrate).

Referring to claim 47, Whitcher discloses a method of making an endoluminal stent (100) comprising vacuum depositing [P0034, P0035, P0036, P0037] nickel and titanium [P0062] onto an exterior surface of a generally cylindrical substrate (105) to form a generally tubular film of nickel-titanium having no less than about 51.5 atomic percent nickel [P0066], table 1, the deposition occurring under process conditions selected to minimize the formation of granular precipitates in the bulk material of a deposited tubular unpatterned crystalline film (P0038-P0040, P0043, P0049, P0061, example 1), and removing the stent from the substrate [0051, 0052, 0053].

Referring back to the limitation, process condition "selected to minimize" granular precipitates, granular precipitates are categorized in the applicants specification as "material properties" and are part of the microstructure see pg.10, lines 12-16. The applicant's specification discloses that the material properties, including the granular precipitates, are controlled or minimized by the actual deposition process, see pg.11, lines 11-15; pg.11 line 30-pg.12, line 2; pg.12, lines 11-13; pg.14, lines 1-12, 19-21. That is, Applicant's disclosure points simply to a vacuum deposition process (sputtering and ion-beam evaporation; pg.11, lines 11-24) as *the means for minimizing precipitates*. Whitcher discloses use of the same vacuum deposition processes (sputtering, ion beam deposition, etc., P0034-P0037) and the use of the same materials used by the applicant (P0062) therefore, inherently Whitcher is controlling and minimizing material properties such as granular precipitates just as much as the applicants are.

Further, Whitcher specifically discloses *accurately and precisely controlling* the composition and microcrystal structure to have the desired mechanical properties [P0011, 0028, 0038, 0042, 0043], therefore, inherently the granular precipitates are controlled, since granular

precipitates are an element of a materials microstructure and the material's mechanical properties, the microstructure and properties which are disclosed to be controlled.

Additionally, Whitcher discloses *selection* of a process *condition.* Whitcher discloses selection of a temperature, pressure, and rate during deposition, therefore, inherently the precipitates are being controlled, since amount and size of the granular precipitates are dependent upon temp, pressure, and rate (general process conditions of vacuum deposition, which applicant has disclosed to be the method of minimizing precipitates), and upon selection of these conditions, one has *controlled* the crystal structure outcome of the metal, hence controlled how much formation of precipitates has occurred. Because Whitcher has disclosed a temperature, pressure, and rate, hence the material properties are preselected and are being controlled by the *selection.* Also, every metal has a specific granular makeup, including precipitates, and just by the user *selecting* a specific material to be deposited, the user is *controlling* the grain size, grain phase, granular precipitates, composition, and binding sites etc.

Further, applicant noted in their previous arguments, inherently precipitates are formed in all post treatments such as annealing. Since some of Whitcher's methods disclose depositing a crystalline film, without the use of annealing process, no precipitates would be formed in the first place, thus are already minimized, since no annealing has taken place and the deposited film is crystalline.

Also, applicant has claimed "process conditions selected to *minimize formation* of chemical and intra and inter-granular precipitates", however they have not claimed to what extent (numerical value) such properties are minimized to. No numerical amount has been assigned to "minimized". It is vague and arbitrary what amount "minimize" is. It is unclear how

to interpret such a word, with no exact value. As best as can be interpreted, Whitcher is believed to have "minimized" formation of precipitates, since the disclosed film may be crystalline upon deposition.

Referring to claims 48, 50, and 51, Whitcher discloses a nickel-titanium composition between *about* 51.5 and 55.0 atomic percent nickel, wherein the nickel and titanium is a binary nickel-titanium alloy (table 1), [0062, 0066].

Referring to claim 49, Whitcher discloses the rotation of the substrate during deposition (vector A, [0048]).

Referring to claims 52 and 53, Whitcher discloses imparting a pattern onto the exterior surface of the substrate (105), wherein the pattern is transferred to the film during deposition [0055, 0056], and alternatively, imparting a pattern onto the tubular film after deposition [0054].

(10) Response to Argument

The applicant has argued that "selected to minimize" is not analogous to preselected or predetermined. This argument made by the examiner was in the examiners "response to arguments" section of the final office action, not part of the actual rejection however the examiners response in that action is still believed to be the examiners opinion and it cited below since it was referred to in the appeal brief:

"The applicant has argued that Whitcher does not disclose a process condition selected to minimize formation of intra and inter granular precipitates, and that this property is not inherently controlled in Whitcher. The examiner disagrees. Whitcher clearly discloses precisely controlling the microstructure of a metal, see P0028, P0040, further discloses minimizing precipitates (discloses filtering of impurities and isotopes during deposition, thus precipitates,

P0038). Granular precipitates are a property of the microstructure. When the microstructure is controlled, as disclosed, inherently the granular precipitates are also, since they are an element of the microstructure. Further, *process conditions* are known in the art to comprise temperature, pressure and deposition rate. For any vacuum deposition process, a user must *select* a temperature, pressure, and deposition rate. Therefore, the user has completed the method *under process conditions selected.* What effect occurs (granular precipitates for instance) is inherently being controlled by the *selection* (that is whether there is little or a lot of precipitates changes depending on the users *selection* of the *condition*). "Selected to minimize" is analogous to preselected or predetermined, see 69 USPQ2d 1001, Ferguson Beauregard/Logic Controls, Division of Dover Resources Inc. v. Mega Systems LLC US Court of Appeals Federal Circuit."

The applicant has further argued that Whitcher does not disclose:

1) the deposited film is crystalline and

2) that precipitate formation has been controlled

The examiner disagrees for the below reasons:

1) Whitcher discloses a film that may be deposited in various different forms of crystallinity. It may be deposited as amorphous (low or no crystallinity) and also monocrystalline and nanocrystalline, both crystalline by name. See P0011, "The medical devices also have a *crystallographic structure* that is ***produced by*** the vapor deposition methods of the present invention. Desirable crystallographic structures include amorphous, *nanocrystalline, and monocrystalline* structures." Emphasis added. Whitcher clearly discloses crystalline films (nanocrystalline and monocrystalline) that are as-deposited ("structure ***produced by*** the vapor deposition"-not ***produced by*** post treatment). Whitcher also discloses that the

microstructure (analogous to crystallinity-how crystalline a material is) is controlled by the vapor deposition technique, see P0028. Whitcher also discloses vacuum deposition processes such as ion beam deposition densifies the product, filtering out impurities and purifying the crystal structure of the product, making more crystalline, see P0037-P0038. Whitcher discloses depositing an as-deposited crystalline film (no post-treatment, is deposited in a crystalline state), see P0040 by ion beam, second part of P0043, end of P0048, P0061, and pg.7, claim 1. Although it is true that Whitcher does disclose an embodiment wherein an amorphorous film is deposited and then post-treated to make crystalline (thus not "as-deposited", first part of P0041) this is only one embodiment disclosed by Whitcher and not the embodiment referred to by the examiner in the rejection.

2) Whitcher discloses precisely controlling the material properties and microstructure of the material (by selection of process conditions), and therefore inherently the precipitates are controlled since they are a component of the microstructure, see P0011, P0028, P0037, P0038, P0042, P0062 and above rejection.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Cheryl Miller

Conferees:

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